

DOCKET: 46342/56,72

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:

H. Kikutani, et al.

Serial No:

10/009,330

Filed:

December 3, 2001

For:

SCREENING METHOD USING CD100

#### **CERTIFICATE OF MAILING**

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231 on April 12, 2002.

Bv

Donna M. Tomaso

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

#### TRANSMITTAL LETTER

Applicants submit the following documents as follows:

- 1. Submission of "Sequence Listing", Computer Readable Copy, and/or Amendment Pertaining Thereto for Biotechnology Invention Containing Nucleotide and/or Amino Acid Sequence (Transmittal);
- 2. Copy of Notice to Comply dated February 12, 2002.
- 3. 3.5" Floppy Disk Containing the Sequence Listing,

و بعد المامية الم

H. Kikutani, et al. USSN: 10/009,330 Page 2

4. Statement in Support of Filing and Submission in accordance with 37 CFR §§1.821-1.825 and Sequence Listing Computer Printout;

By:

Respectfully submitted,

Date: April 12, 2002

John B/Alexander, Ph.D.

Reg. No. 48,399

Attorney for Applicant(s)

Dike, Bronstein, Roberts & Cushman Intellectual Property Practice Group EDWARDS & ANGELL, LLP P.O. Box 9169 Boston, MA 02209 Customer No. 21874 (617) 439-4444



Practitioner's Docket No. <u>46342/56,721</u> PATENT

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

H. Kikutani, et al.

Application No.:

10/009,330

Filed:

December 3, 2001

Examiner: Unassigned

Group No.: Unassigned

For: SCREENING METHOD USING CD100

Box Sequence Assistant Commissioner for Patents Washington, D.C. 20231

#### SUBMISSION OF "SEQUENCE LISTING," COMPUTER READABLE COPY, AND/OR AMENDMENT PERTAINING THERETO FOR BIOTECHNOLOGY INVENTION CONTAINING NUCLEOTIDE AND/OR AMINO ACID SEQUENCE

(check and complete this item, if applicable)

1.	[X] This replies to the Office Letter DATED_	February 12, 2002	_

NOTE: If these papers are filed before the office letter issues, adequate identification of the original papers should be made, e.g., in addition to the name of the inventor and title of invention, the filing date based on the "Express Mail" procedure, the application number from the return post card or the attorney's docket number added.

[X] A copy of the Office Letter is enclosed.

#### IDENTIFICATION OF PERSON MAKING STATEMENT

2. I,	John B. Alex	ander, Ph.D
		(type or print name of person signing below)
state t	he following:	

#### ITEMS BEING SUBMITTED

3. Submitted herewith is/are:

(check each item as applicable)

A. [X] "Sequence Listing(s)" for the nucleotide and/or amino acid sequence(s) in this application. Each "Sequence Listing" is assigned a separate identifier as required in 37 C.F.R. Section 1.821(c) and 37 C.F.R. Sections 1.822 and 1.823.

B.		ption and/or claims, wherein reference is made to the sequence ifier, as required in 37 C.F.R. Section 1.821(d).	by
C.		Listing" submitted for this application in computer readable for equirements of 37 C.F.R. Sections 1.821(e) and 1.824.	rm,
D.		ation, in accordance with 37 C.F.R. Section 1.821(e), the computable applicant's other application identified as follows:	ıter
	In re application of: Application No.: 0 / Filed: For:	Group No.: Examiner:	
	e Computer readable form(s) of the application as follows	of applicant's other application corresponds to the "Sequents:	nce
Comp	outer Readable Form	"Sequence Identifier	Γ**
(other	application)	(this application	1)
NOTE:	application of the applicant on file in th form in lieu of filing a duplicate con	ew application is to be identical with the computer readable form of anotate Office, reference maybe made to the other application and computer readal inputer readable form in the new application. The new application shall reference to the other application and computer readable form, both of wh	ble be
Ė.		ent of each "Sequence Listing" submitted and each compute as required in 37 C.F.R. Section 1.821(g).	ter
		s not made by a person registered to practice before the Office as required in 37 C.F.R. Section 1.821(b).	ce,
F.		s made in fulfilling the requirement under 37 C.F.R. Section e submission includes no new matter.	on
	[ ] Because the statement is the statement is verified,	s not made by a person registered to practice before the Office, as required in 37 C.F.R. Section 1.821(g).	:e,

**强** 

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# STATEMENT THAT "SEQUENCE LISTING" AND COMPUTER READABLE COPY ARE THE SAME AND/OR THAT PAPERS SUBMITTED INCLUDES NO NEW MATTER

4. I hereby state:

(complete applicable item A and/or B)

- A. [X] Each computer readable form submitted in this application, including those forms requested to be transferred from applicant's other application, is the same as the "Sequence Listing" to which it is indicated to relate.
- B. [X] All papers accompanying this submission, or for which a request for transfer from applicants' other application, introduce no new matter.

#### STATUS

	SIAIUS
5.	Applicant is
	[ ] a small entity. A statement:
	[ ] is attached.
	[ ] was already filed.
	[X] other than a small entity.
	EXTENSION OF TERM
6. <i>NO</i> I	E: "Extension of Time in Patent Cases (Supplement Amendments) If a timely and complete response has been filed after a Non-Final Office Action, an extension of time is not required to permit filing and/or entry of an additional amendment after expiration of the shortened statutory period.  If a timely response has been filed after a Final Office Action, an extension of time is required to permit filing and/or entry of a Notice of Appeal or filing and/or entry of an additional amendment after expiration of the shortened statutory period unless the timely-filed response placed the application in condition for allowance. Of course, if a Notice of Appeal has been filed within the shortened statutory period, the period has ceased to run." Notice of Dec. 10, 1985 (1061 O.G. 34-35).

NOTE: See 37 C.F.R. Section 1.645 for extensions of time in interference proceedings and 37 C.F.R. Section 1.550(c) for extensions of time in reexamination proceedings.

7. The proceedings herein are for a patent application and the provisions of 37 C.F.R. Section 1.136 apply.

#### (complete (a) or (b) as applicable)

(a) [X] Applicant petitions for an extension of time under 37 C.F.R. Section 1.136 (fees: 37 C.F.R. Section 1.17(a)(1)-(4)) for the total number of months checked below:

	Extension (months)	Fee for other than small entity	Fee for small entity		
[ ] [] [ ]	one month two months three months four months	\$ 110.00 \$ 400.00 \$ 920.00 \$1440.00	\$ 55.00 \$ 200.00 \$ 460.00 \$ 720.00		
		Fee \$			
If an additi	If an additional extension of time is required, please consider this a petition therefor.  (check and complete the next item, if applicable)				
[ ] An extension for months has already been secured, and the fee paid therefor of \$ is deducted from the total fee due for the total months of extension now requested.					
		Extens	ion fee due with this request \$		
		OR			
(b) [ <b>X</b>	(b) [X] Applicant believes that no extension of term is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition and fee for extension of time.				
		FFF DAVA	AFNT		

#### **FEE PAYMENT**

8.	[ ] Attached is a check in the su	m of \$	
	[ ] Charge Account No	the sum of \$	
	A duplicate of this transmitt	al is attached.	

#### **FEE DEFICIENCY**

9.

NOTE: If there is a fee deficiency and there is no authorization to charge an account, additional fees are necessary to cover the additional time consumed in making up the original deficiency. If the maximum, six-month period has expired before the deficiency is noted and corrected, the application is held abandoned. In those instances where authorization to charge is included, processing delays are encountered in returning the papers to the PTO finance Branch in order to apply these charges prior to action on the cases. Authorization to charge the deposit account for any fee deficiency should be checked. See the Notice of April 7, 1986, 1065 O.G. 31-33.

	SIGNATURE(s)
	John B. Alexander, Ph.D.  (type or print name of person signing statement)  Signature
April 12, 2002	V
Date	
Intellectual Property Practice Group EDWARDS & ANGELL, LLP P. O. Box 9169, Boston, MA 02209	
	[ ] Inventor
(If applicable)	[ ] Assignee of complete interest [ ] Person authorized to sign on behalf of assignee **
Tel. No.: (617) – 439-4444	[X] Practitioner of record
Fax Nos.: (617) 439-4170	[ ] Filed under Rule 34(a)
Customer No.: 21874	[X] Registration No. 48,399  Other
	(specify identity of person signing)
(complete	the following, if applicable)
(type name of assignee)	-
Address of assignee	·

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#### UNITED STATES PATENT AND TRADEMARK OFFICE



Contrassioner for Palmits, Box PCT United States Patent and Tradomark Office Washington, D.C. 2023 part upply ace

U.S. APPLICATION NUMBER NO.

FIRST NAMED APPLICANT

ATTY. DOCKET NO.

10/009,330

Hitoshi kikutani

46342/56,721

INTERNATIONAL APPLICATION NO.

PCT/JP00/03558

LA. FILING DATE

PRIORITY DATE

06/01/2000

06/03/1999

Cara Z Lowen Dike Bronstein Roberts & Cushman P O Box 9169 Boston, MA 02209

RECEIVED FEB 2 1 2002 EDWARDS & ANGELL LLP DIKE BRONSTEIN ROBERTS CUSHMAN

**CONFIRMATION NO. 3836 371 FORMALITIES LETTER** 

OC000000007452830\*

Date Mailed: 02/12/2002

### NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as an Elected Office (37 CFR 1.495):

- U.S. Basic National Fees
- Priority Document
- Assignee Statement
- Biochemical Sequence Diskette
- Biochemical Sequence Listing
- Copy of IPE Report
- Copy of references cited in ISR
- Copy of the International Application
- Copy of the International Search Report
- Information Disclosure Statements
- Oath or Declaration

Jequena Listin

Edwards & Angell LLP

Dike, Bronstein, Roberts & Cushman

101 Federal St. Boston, MA 02110

Date Rec'd 2/21/0 2

Docketed For And

Approved.

The following items MUST be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTH FROM THE DATE OF THIS NOTICE OR BY 22 or 32 MONTHS (where 37 CFR 1.495 applies) FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

The following items MUST be furnished within the period set forth below:

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the

requirements for such a disclosure as set forth in 37 CFR 1.821-1.825 for the following reason(s):

- RAW SEQUENCE LISTING ERROR REPORT
- APPLICANT MUST PROVIDE:
  - An initial or substitute paper copy or compact disc of the "Sequence Listing," as well as an amendment directing its entry into the specification.
- For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:
  - For Rules Interpretation, call (703) 308-4216
  - To Purchase Patentin Software, call (703) 306-2600
  - For Patentin Software Program Help, call (703) 306-4119 or e-mail at patin21help@uspto.gov or patin3help@uspto.gov

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

A copy of this notice MUST be returned with the response.

#### FREDERICK SMITH

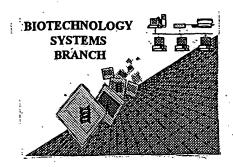
Telephone: (703) 305-3654

#### PART 1 - ATTORNEY/APPLICANT COPY

	1-1000	
U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/009,330	PCT/JP00/03558	46342/56,721

FORM PCT/DO/EO/905 (371 Formalities Notice)

## RAW SEQUENCE LISTING ERROR REPORT



The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following computer readable form:

Application Serial Number:	10/009,330	
Source:	PCT	
Date Processed by STIC:		14/2002

THE ATTACHED PRINTOUT EXPLAINS DETECTED ERRORS.
PLEASE FORWARD THIS INFORMATION TO THE APPLICANT BY EITHER:

- 1) INCLUDING A COPY OF THIS PRINTOUT IN YOUR NEXT COMMUNICATION TO THE APPLICANT, WITH A NOTICE TO COMPLY or,
- 2) TELEPHONING APPLICANT AND FAXING A COPY OF THIS PRINTOUT, WITH A NOTICE TO COMPLY

FOR CRF SUBMISSION QUESTIONS, PLEASE CONTACT MARK SPENCER, 703-308-4212.

FOR SEQUENCE RULES INTERPRETATION, PLEASE CONTACT ROBERT WAX, 703-308-4216. PATENTIN 2.1 e-mail help: patin21help@uspto.gov or phone 703-306-4119 (R. Wax) PATENTIN 3.0 e-mail help: patin3help@uspto.gov or phone 703-306-4119 (R. Wax)

TO REDUCE ERRORED SEQUENCE LISTINGS, PLEASE USE THE CHECKER VERSION 3.1 PROGRAM, ACCESSIBLE THROUGH THE U.S. PATENT AND TRADEMARK OFFICE WEBSITE. SEE BELOW FOR ADDRESS:

http://www.uspto.gov/web/offices/pac/checker

Applicants submitting genetic sequence information electronically on diskette or CD-Rom should be aware that there is a possibility that the disk/CD-Rom may have been affected by treatment given to all incoming mail. Please consider using alternate methods of submission for the disk/CD-Rom or replacement disk/CD-Rom, including:

- 1. EFS-Bio (<a href="http://www.uspto.gov/ebc/efs/downloads/documents.htm">http://www.uspto.gov/ebc/efs/downloads/documents.htm</a>, EFS Submission User Manual ePAVE)
- 2. U.S. Patent and Trademark Office, Box Sequence, P.O. Box 2327, Arlington, VA 22202
- Hand Carry directly to:
   U.S. Patent and Trademark Office, Technology Center 1600, Reception Area, 7<sup>th</sup> Floor, Examiner Name, Sequence Information, Crystal Mall One, 1911 South Clark Street, Arlington, VA 22202
  - U.S. Patent and Trademark Office, Box Sequence, Customer Window, Lobby, Room 1B03, Crystal Plaza Two, 2011 South Clark Place, Arlington, VA 22202
- 4. Federal Express, United Parcel Service, or other delivery service to: U.S. Patent and Trademark Office, Box Sequence, Room 1B03-Mailroom, Crystal Plaza Two, 2011 South Clark Place, Arlington, VA 22202

-	///
ERROR DETECTED	SUGGESTED CORRECTION SERIAL NUMBER: 109350
TTN: NEW RULES CASES	: PLEASE DISREGARD ENGLISH "ALPHA" HEADERS, WHICH WERE INSERTED BY PTO SO
lWrapped Nucleics Wrapped Aminos	The number/text at the end of each line "wrapped" down to the next line. This may occur if your file was retrieved in a word processor after creating it. Please adjust your right margin to .3; this will prevent "wrapping."
2Invalid Line Length	The rules require that a line not exceed 72 characters in length. This includes white spaces.
3Misaligned Amino Numbering	The numbering under each 5th amino acid is misaligned. Do not use tab codes between numbers; use space characters, instead.
4Non-ASCII	The submitted file was not saved in ASCII(DOS) text, as required by the Sequence Rules. Please ensure your subsequent submission is saved in ASCII text.
SVariable Length	Sequence(s) contain n's or Xaa's representing more than one résidue. Per Sequence Rules, each n or Xaa can only represent a single residue. Please present the maximum number of each residue having variable length and indicate in the <220>-<223> section that some may be missing.
6PatentIn 2.0 "bug"	A "bug" in PatentIn version 2.0 has esused the <220>-<223> section to be missing from amino acid sequences(s) Normally, Patentin would automatically generate this section from the previously coded nucleic acid sequence. Please manually copy the relevant <220>-<223> section to the subsequent amino acid sequence. This applies to the mandatory <220>-<223> sections for Artificial or Unknown sequences.
7Skipped Sequences (OLD RULES)	Sequence(s) missing. If intentional, please insert the following lines for each skipped sequence: (2) INFORMATION FOR SEQ ID NO:X: (insert SEQ ID NO where "X" is shown) (i) SEQUENCE CHARACTERISTICS: (Do not insert any subheadings under this heading). (xi) SEQUENCE DESCRIPTION:SEQ ID NO:X: (insert SEQ ID NO where "X" is shown) This sequence is intentionally skipped
	Please also adjust the "(ii) NUMBER OF SEQUENCES:" response to include the skipped sequences.
8Skipped Sequences (NEW RULES)	Sequence(s) missing. If Intentional, please insert the following lines for each skipped sequence. <210> sequence id number <400> sequence id number 000
	-
Use of n's or Xaa's (NEW RULES)	Use of n's and/or Xaa's have been detected in the Sequence Listing.  Per 1.823 of Sequence Rules, use of <220>-<223> is MANDATORY if n's or Xaa's are present.  In <220> to <223> section, please explain location of n or Xaa, and which residue n or Xaa represents.
0invalid <213> Response	Per 1.823 of Sequence Rules, the only valld <213> responses are: Unknown, Artificial Sequence, or scientific name (Genus/species). <220>-<223> section is required when <213> response is Unknown or is Artificial Sequence
1Use of <220>	Sequence(s) /O missing the <220> "Feature" and associated numeric identifiers and responses. Use of <220> to <223> is MANDATORY if <213> "Organism" response is "Artificial Sequence" or "Unknown." Please explain source of genetic material in <220> to <223> section. (See "Federal Register," 06/01/1998, Vol. 63, No. 104, pp. 29631-32) (Sec. 1.823 of Sequence Rules)
2PatentIn 2.0 "bug"	Please do not use "Copy to Disk" function of Patentln version 2.0. This causes a corrupted file, resulting in missing mandatory numeric identifiers and responses (as indicated on raw sequence listing). Instead, please use "File Manager" or any other manual means to copy file to floppy disk.
3Misuse of n	n can only be used to represent a single nucleotide in a nucleic acid sequence. N is not used to represent any value not specifically a nucleotide.

AMC/MH - Biotechnology Systems Branch - 08/21/2001

DATE: 01/14/2002 TIME: 13:43:57

PCT10

```
Input Set : A:\Sequence Listing.txt
                     Output Set: N:\CRF3\01142002\J009330.raw
                                                                            Does Not Comply
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                                                                       Corrected Diskette Needed
W-->
      4 <120> TITLE OF INVENTION: Screening Method Using CD100
      5 <130> FILE REFERENCE: 2611WOOP
        <140> CURRENT APPLICATION NUMBER: US/10/009,330
      6 <141> CURRENT FILING DATE: 2001-12-03
      6 <150> PRIOR APPLICATION NUMBER: JP 11-157111
      7 <151> PRIOR FILING DATE: 1999-06-03
        <160> NUMBER OF SEQ ID: 10
ERRORED SEQUENCES
     414 <211> LENGTH: (1357) 1337 SLOWN
415 <212> TYPE
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     416 <213> ORGANISM: Mouse
(W/6-> 417 <400> SEQUENCE: 6
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                                                                               60
     419 tgcgctttgt gaaagtgccc ctgaagaaca gcgcatctaa ccatctagga caggactgtg
                                                                              120
     420 aggectatga agatggggaa eteacetaeg agaatgtgea agtgteteea gteecaggag
                                                                              180
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                                                                              240
     422 caactgcgac ctggagetet gtgaactcgt ctgeteteag geagatteee egetgteeta
                                                                              300
     423 cagtetgett geaataette ttgettggee ttetegtgte etgtetgatg ttaggggtgg
                                                                              360
     424 ctgtcatctg cctgggagtt cgctatctgc aggtgtctcg gcagttccag gaggggacca
                                                                              420
     425 ggatttggga agccaccaat agcagcctgc agcagcagct cagggagaag ataagtcagc
                                                                              480
     426 tggggcagaa ggaggtggag cttcagaagg ctcggaaaga gctgatctcg agccaggaca
     427 cattacagga gaagcagagg actcacgagg acgctgagca gcaactacaa gcctgccagg
                                                                              600
     428 ctgagagagc gaagaccaag gagaacctga aaactgagga ggagcggagg agggacctgg
                                                                              660
     429 accagaggit gacaagcacg cgggagacac tgaggcgctt citcictgat tcatcagaca
                                                                              720
     430 cctgctgtcc atgcggatgg attccatatc aggaaaggtg cttttacatc tcacataccc
     431 toggaagtot ggaggagago caaaaatact gcacatotot gtootocaaa ctggcagcat
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     433 tagatogtto gaagtoatat tggatacaga tgagcaagaa gtggaggcag gactotgact
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     436 ggatcaatct gaactgaaac ggacacttga acaagacett gtgacctaca teettaacet 1140
     437 acggeetgee aattittaag actgetatte etceageact eceteactet egggeatgee 1200
     438 cagetaaggg atgacetget gettgettga aagetgetee agaaactgga ettetettgg 1260
E--> 439 gaagagtaaa gaagcctcca gaaaagactt gaccttcctt aagaacttcc caaactagag(1340)|320
E--> 440 atgggtcagg ggagggc
     531 <210> SEQ ID NO: 10
     532 <211> LENGTH: 53
                                         see item 11 on Evan Summary Sheet
see next page
     533 <212> TYPE: DNA
     534 <213> ORGANISM: (Artificial Sequence
  -> 535 <220 > FEATURE:
     536 <223> JOTHER INFORMATION:
₩<mark>){> 537 ₹400</mark>> SEQUENCE: 10
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RAW SEQUENCE LISTING

PATENT APPLICATION: US/10/009,330

RAW SEQUENCE LISTING

DATE: 01/14/2002

PATENT APPLICATION: US/10/009,330

TIME: 13:43:57

Input Set : A:\Sequence Listing.txt

Output Set: N:\CRF3\01142002\J009330.raw

538 gacggatcct acttactttg ctttgcttgc ttgagataca ccgtcttctc tga

53

E--> 543(1)

VERIFICATION SUMMARY DATE: 01/14/2002 PATENT APPLICATION: US/10/009,330 TIME: 13:43:58

Input Set : A:\Sequence Listing.txt
Output Set: N:\CRF3\01142002\J009330.raw

L:4 M:283 W: Missing Blank Line separator, <120> field identifier L:5 M:283 W: Missing Blank Line separator, <130> field identifier L:6 M:270 C: Current Application Number differs, Replaced Current Application No L:6 M:271 C: Current Filing Date differs, Replaced Current Filing Date L:8 M:283 W: Missing Blank Line separator, <160> field identifier L:9 M:283 W: Missing Blank Line separator, <210> field identifier L:13 M:283 W: Missing Blank Line separator, <400> field identifier L:126 M:283 W: Missing Blank Line separator, <400> field identifier L:178 M:283 W: Missing Blank Line separator, <400> field identifier L:291 M:283 W: Missing Blank Line separator, <400> field identifier L:366 M:283 W: Missing Blank Line separator, <400> field identifier L:417 M:283 W: Missing Blank Line separator, <400> field identifier L:439 M:254 E: No. of Bases conflict, LENGTH:Input:1340 Counted:1320 SEQ:6 M:254 Repeated in SeqNo=6 L:440 M:252 E: No. of Seq. differs, <211>LENGTH:Input:1357 Found:1337 SEQ:6 L:445 M:283 W: Missing Blank Line separator, <400> field identifier L:496 M:283 W: Missing Blank Line separator, <400> field identifier L:527 M:283 W: Missing Blank Line separator, <220> field identifier L:529 M:283 W: Missing Blank Line separator, <400> field identifier L:535 M:283 W: Missing Blank Line separator, <220> field identifier L:537 M:283 W: Missing Blank Line separator, <400> field identifier L:543 M:254 E: No. of Bases conflict, LENGTH:Input:1 Counted:53 SEQ:10